UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,647	09/04/2003	Robert A. VanTassel	4056	8112
	7590 03/12/200 YSVER P.L.L.C.	9	EXAMINER BUI, VY Q  ART UNIT PAPER NUMBER 3773	INER
	S AVENUE SOUTH		BUI, VY Q	
MINNEAPOLI	S, MN 55416		ART UNIT	PAPER NUMBER
			3773	
			MAIL DATE	DELIVERY MODE
			03/12/2009	PAPER

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)	
	10/656,647	VANTASSEL ET AL.	
Office Action Summary	Examiner	Art Unit	
	Vy Q. Bui	3773	
The MAILING DATE of this communica Period for Reply	ntion appears on the cover sheet	vith the correspondence address -	=
A SHORTENED STATUTORY PERIOD FOR WHICHEVER IS LONGER, FROM THE MAI  - Extensions of time may be available under the provisions of after SIX (6) MONTHS from the mailing date of this communi  - If NO period for reply is specified above, the maximum statut  - Failure to reply within the set or extended period for reply will Any reply received by the Office later than three months after earned patent term adjustment. See 37 CFR 1.704(b).	LING DATE OF THIS COMMUN 37 CFR 1.136(a). In no event, however, may a ication. ory period will apply and will expire SIX (6) MO I, by statute, cause the application to become	ICATION. A reply be timely filed  DNTHS from the mailing date of this communical ABANDONED (35 U.S.C. § 133).	
Status			
Responsive to communication(s) filed (2a)    This action is <b>FINAL</b> . 2b	)☐ This action is non-final. r allowance except for formal ma		s is
Disposition of Claims			
4)  Claim(s) 1-7 is/are pending in the appliance 4a) Of the above claim(s) 2 and 3 is/are 5)  Claim(s) is/are allowed. 6)  Claim(s) 1 and 4-7 is/are rejected. 7)  Claim(s) is/are objected to. 8)  Claim(s) are subject to restriction  Application Papers 9) The specification is objected to by the E	e withdrawn from consideration. on and/or election requirement.		
10) The drawing(s) filed on is/are: a Applicant may not request that any objection Replacement drawing sheet(s) including the second or declaration is objected to be	on to the drawing(s) be held in abeyone correction is required if the drawing	ance. See 37 CFR 1.85(a). g(s) is objected to. See 37 CFR 1.12	
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for a) All b) Some * c) None of:  1. Certified copies of the priority do  2. Certified copies of the priority do  3. Copies of the certified copies of application from the International	ocuments have been received. Ocuments have been received in the priority documents have been all Bureau (PCT Rule 17.2(a)).	Application No n received in this National Stage	
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTC 3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date	)-948) Paper No	Summary (PTO-413) o(s)/Mail Date Informal Patent Application 	

#### **DETAILED ACTION**

#### Election/Restrictions

Claims 2-3 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/1/2007.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 4-6 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lesh et al-6,152,144.

Application/Control Number: 10/656,647 Page 3

Art Unit: 3773

As to claims 1, 4-6, Lesh-'144's Fig. 6-8, 11-12 and col. 9, lines 15-33, for example, show a occluding device for prevention of an embolic stroke comprising mesh membrane 61/107, expandable support structure 65/103, which can be expandable by a balloon or by a self expanding mechanism (col. 9, lines 15-42) and a method substantially as recited in the claims. Notice that mesh membrane 61/107 as shown in Fig. 6-8, 11-12 should allow blood flowing through and prevent any blot clot or thrombus having a size bigger than the mesh opening to go through. Especially, when the openings or pores in the membrane 61/107 are sized to about 0.04" (about 1mm) as disclosed in the Lesh-'144's reference (col. 9, lines 15-42), the blood cells (red cells are about 6-8 micrometers in diameter and 2 micro meters in thickness) inherently must be able to flow through these pores/openings but not the stenosis having size bigger than 0.04".

It is well known in the art to prevent blood clot or thrombus to flow freely in a vascular system to prevent an embolic stroke to occur. Alternatively, it would have been obvious to one of ordinary skill in the art to provide mesh membrane 61/107 with pores or openings properly sized to prevent blood clot or thrombus going through the membrane and into a vascular system of a patient so that one can prevent an embolic stroke.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lesh et al-6,152,144.

As to claim 7, Lesh-'144 discloses substantially a device and a method of preventing an embolic stroke substantially as recited in the claims except for removing the expandable structure through an opening in Lesh-'144's membrane 61 after expanding the support structure 65 (Fig. 6-8). However, Lesh-'144 (col. 9, lines 15-33) discloses a balloon to expand support structure 65 and a lumen with a self sealing valve in hub 73 for receiving a guidewire of guiding member. The self sealing valve will prevent a passage of fluid or embolic material once the guidewire or guiding member is removed from the lumen. It would have been obvious to one of ordinary skill in the art to provide balloon catheter through the lumen in hub 73 (or opening in the membrane 61) to expand the support structure 65 and then withdraw the balloon from a left atrial appendage after the support structure 65 has been expanded by the balloon, as the lumen in hub 73 is the one passage way available for introducing and removing the balloon catheter.

### Response to Arguments

Applicant's arguments filed 10/23/2008 have been fully considered but they are not persuasive.

As mentioned above, the pores/openings of membrane 63 can be as large as 0.004" (about 1mm). Inherently, blood cells can go through membrane 63 and not the thrombus having sizes bigger than 0.004".

In addition, one of ordinary skill in the art can recognize that the self-sealing valved lumen in hub 73 can be conveniently used to introduce a balloon catheter to expand support structure 65 and then withdraw the catheter balloon afterward in a manner as recited in claim 7.

#### Conclusion

**THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 571-272-4692. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vy Q. Bui/ Primary Examiner, Art Unit 3773